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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,866	05/16/2005	Kenneth J. Ruchala	013869-9005-01	4683
23409 7590 04/29/2010 MICHAEL BEST & FRIEDRICH LLP 100 E WISCONSIN AVENUE Suite 3300 MILWAUKEE, WI 53202				
EXAMINER				
KISH, JAMES M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,866

Applicant(s)

RUCHALA ET AL.

Examiner

JAMES KISH

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed March 2, 2010 have been fully considered but they are not persuasive.

The Applicant argues that the prior art references of record fail to teach each element of the independent claims. The Examiner respectfully disagrees.

Miller teaches a majority of the aspects of the independent claims. For instance, with respect to claim 27 Miller teaches, "obtaining at least one treatment planning image from a patient to determine the relative location of target and sensitive structures; preparing a treatment plan for the patient based on the at least one treatment planning image, [the treatment plan including a planned dose distribution]; obtaining at least one [three-dimensional] image from the patient in substantially a treatment position, the [three-dimensional] image including anatomical data and being used for [volumetric] dose calculations; comparing the at least one treatment planning image and the at least one [three-dimensional] image; and adjusting how the dose is received by the patient based on the comparison." This has been described in the previous Office Actions.

Frohlich teaches the failure of Miller to define the treatment plan as including a planned dose distribution.

Robar teaches "the creation of volumetric data sets from multiple two-dimensional analog images. Embodiments of the invention provide both methods for assembling a number of two-dimensional images into a volumetric data set and automated systems for performing such methods. The invention has particular

application in the generation of volumetric data sets representing the spatial distribution of absorbed radiation dose for radiation exposures to be used in conformal radiosurgery." Therefore, Robar teaches creating volumetric data sets from two-dimensional data sets and suggests that this is useful in radiosurgery. Miller would be enhanced by these teachings in that the CT scans of Miller would be compared to corresponding three-dimensional images, rather than three-dimensional CT scans in comparison with two-dimensional scans.

Therefore, the prior art references teach each limitation of the independent claims and the rejection is repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US Patent No. 5,117,829) – herein referred to as Miller – in view of Frohlich (US Patent Pub. No. 2002/0080915), and further in view of Robar et al. (US Patent Pub. No. 2001/0033682) – herein referred to as Robar. Miller discloses patient alignment systems and procedures for radiation treatment. Figure 8 illustrates a flowchart of the procedure. As can be seen in this figure, a patient is first exposed to an imaging procedure within a pod. The pod is used to repeatedly reposition the patient for the treatment process and, therefore, when the patient is in the pod he or she is considered to be in a treatment position. The patient is then transported within the pod to a treatment room and the table on which the patient and pod are attached is adjusted to settings determined by a treatment plan. Therefore, a treatment plan has already been created at this time. More images of the patient are acquired at this point in time. Corrections may be made, if they are required. If corrections are not required, treatment begins and adjustments may be made at any time once the treatment phase has begun. However, while it would be obvious to one of ordinary skill in the art that a treatment plan would include a dose distribution in radiation therapy, it is not explicitly stated within Miller that this is included within the treatment plan. Frohlich teaches a planning method and apparatus for radiotherapy treatment of a target volume in a body. The methods described by Frohlich "directly define the desired dose distribution instead

of defining beam parameters. The desired dose distribution may be defined in different ways, e.g. by drawing on the two-dimensional (2D) CT slices (paragraph 6)." That paragraph also states that dose distribution may be determined via dose volume histograms (or DVH). Paragraph 11 describes the use of objective functions while paragraph 12 states that multiple treatment solutions are obtained. Paragraph 30-32 further describes multiple plan determination and benefits. Paragraph 25 teaches several imaging modalities that may be used to acquire images for the procedure. Therefore, it would be obvious to one of ordinary skill in the art that dose distributions may be determined via 2D images of a volume to be treated and it would be obvious to one of ordinary skill in the art to include a dose distribution plan in the treatment planning, as it is described and taught in Figure 8 of Miller, in order to later perform radiation therapy. Furthermore, the ability of Frohlich to create multiple treatment plans would improve the methods of Miller by removing the need for "gathering new CT scan data and formulating a new treatment plan (column 15, lines 66-67)," thereby saving time and money. However, neither Miller nor Frohlich teach that a three-dimensional image is used for volumetric dose calculations and used to compare with the treatment planning image.

Robar teaches a method for creating a volumetric data set representing a three-dimensional distribution, such as a dose distribution produced by a radiosurgery system (see Abstract). Upon creation of the three-dimensional dose distribution created by Robar, this image may be "spatially co-registered in treatment planning software for comparison with an intended dose distribution (see paragraph 45)." "Any deviations of

the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient. The radiosurgery plan can be adjusted to correct these deviations (see paragraph 46)." It would be obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Robar to create a three-dimensional image of dose distribution for comparison with the three-dimensional images used in the treatment plan of Miller so that "Any deviations of the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient (see paragraph 46)."

Regarding new claims 28-31, the Examiner notes that these claims correspond to similar subject matter that was incorporated in now canceled claim 14. These features of the invention still read on the Miller reference as previously described and are rejected as such.

Regarding claims 33 and 35-39, these claims relate directly to original, now canceled claims 16-39, respectively. These claims are rejected over Miller as in the previous Office Actions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

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